NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

BARBARA STROUGO, Individually and on Behalf of All Others Similarly Situated, Plaintiff, v. MALLINCKRODT PUBLIC LIMITED COMPANY, *et al.*, Defendants.	Civil Action No. 20-10100 (MAS) (TJB) **MEMORANDUM OPINION**

SHIPP, District Judge

This class action matter comes before the Court on Defendants Mark C. Trudeau ("Trudeau"), Matthew K. Harbaugh ("Harbaugh"), George A. Kegler ("Kegler"), Bryan M. Reasons ("Reasons"), Kathleen A. Schaefer ("Schaefer"), Angus C. Russell ("Russell"), Melvin D. Booth ("Booth"), JoAnn A. Reed ("Reed"), Paul R. Carter ("Carter"), and Mark J. Casey's ("Casey") (collectively, "Defendants") Motion to Dismiss Lead Plaintiff Canadian Elevator Industry Pension Trust Fund's ("Plaintiff") Amended Complaint.[1] (ECF No. 79.) Plaintiff opposed (ECF No. 84) and Defendants replied (ECF No. 95). The Court has carefully reviewed the parties'

[1] The Court approved Mallinckrodt PLC's ("Mallinckrodt") Chapter 11 bankruptcy plan as of April 27, 2022, rendering it no longer a defendant in this matter by operation of law. (ECF No. 99; *see* ECF No. 104 (Order of voluntary dismissal of Mallinckrodt).) A more thorough explanation of this history is below.

submissions and decides the matter without oral argument under Local Civil Rule 78.1. For the reasons below, the Court denies Defendants' Motion.[2]

I. BACKGROUND[3]

A. Overview of the Litigation

This is a case about Defendants allegedly underpaying rebates for the product H.P. Acthar Gel ("Acthar"), which resulted in a federal securities class action on behalf of all purchasers of the common stock of Mallinckrodt between May 3, 2016 and March 18, 2020 (the "Class Period"). (Am. Compl. ¶ 1, ECF No. 56.) Plaintiff asserts claims against certain of Mallinckrodt's senior executives and directors for violations of § 10(b) of the Securities Exchange Act of 1934 (the "Exchange Act," 15 U.S.C. §§ 78j(b) and 78t(a)) and Securities and Exchange Commission ("SEC") Rule l0b-5 promulgated thereunder (17 C.F.R. § 240.10b-5), as amended by the Private

[2] Plaintiff submitted a sur-reply (ECF No. 99), Defendants submitted an opposition to the sur-reply (ECF No. 101), and Plaintiff replied (ECF No. 102). Although such submissions are restricted by Local Civil Rule 7.1(d)(6), the Court nevertheless considered the arguments raised in the parties' supplemental submissions. *See* L. Civ. R. 7.1(d)(6); *see also* L. Civ. R. 83.2(b) ("any Rule may be relaxed or dispensed with by the Court if adherence would result in . . . injustice").

[3] For the purpose of considering the instant Motion, the Court accepts all factual allegations in the Amended Complaint as true. *See Phillips v. County of Allegheny*, 515 F.3d 224, 233 (3d Cir. 2008). Defendants also ask the Court to judicially notice thirty-four documents. (Defs.' Moving Br. 5 n.2.) Plaintiff avers that the first five of these exhibits cannot be judicially noticed because they are submitted for their truth or are subject to reasonable dispute and thus, impermissible under this Court's precedent. (Pl.'s Opp'n Br. 12-13.) Defendants' exhibits, however, consist of SEC filings, earnings call transcripts, government websites, and documents upon which the Amended Complaint cites and relies, some of which were filed in the CMS Litigation (defined below). These exhibits thus fall into categories that are subject to judicial notice. *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1426 (3d Cir. 1997) (documents "integral to or explicitly relied upon in the complaint"); *United States ex rel. Perri v. Novartis Pharm. Corp.*, 2019 WL 6880006, at *15 n.15 (D.N.J. Feb. 21, 2019) ("published reports of federal administrative bodies"); *Sapir v. Averback*, No. 14-7331, 2016 WL 554581, at *10 (D.N.J. Feb. 10, 2016) ("SEC filings, press releases, and earnings call transcripts"); *Cohen v. Telsey*, No. 09-2033, 2009 WL 3747059, at *6 (D.N.J. Nov. 2, 2009) ("documents filed in other courts"). The Court, accordingly, considers each of the exhibits attached to Defendants' Motion.

Securities Litigation Reform Act of 1995 ("PSLRA"), § 78u–4 (*Count I*), and for violations of § 20(a) of the Exchange Act (*Count II*). (*See generally* Am. Compl.) As a remedy, Plaintiff seeks compensatory damages in favor of Plaintiff and the Class against all Defendants, jointly and severally, for all damages. (Am. Compl. 76.)

B. Acthar and its Price Rise

Mallinckrodt is a pharmaceutical company whose highest selling product during the Class Period was Acthar, which generated at least thirty-four percent of the Company's net sales annually during this time. (*Id.* ¶¶ 2, 50-64.) Acthar was approved by the Food and Drug Administration ("FDA") in 1952 under new drug application ("NDA") 008372 to treat numerous diseases. (*Id.* ¶¶ 58-66, 102.) By 2001, Acthar cost forty dollars per five milliliter vial, the standard dose. (*Id.* ¶ 67.) In June 2006, Questcor Pharmaceuticals, Inc. ("Questcor"), Acthar's then-owner, submitted a supplemental NDA ("sNDA") to the FDA to obtain approval for Acthar to treat infantile spasms, an indication not included in the FDA's original approval of Acthar. (*Id.* ¶¶ 68-69.) By August 2007, Questcor had raised Acthar's price to $23,000 per five milliliter vial in anticipation of receiving FDA approval to treat infantile spasms. (*Id.* ¶ 70.) In October 2010, the FDA approved adding infantile spasms to Acthar's label as an additional indication. (*Id.* ¶ 71.) On April 7, 2014, Trudeau announced that Mallinckrodt was acquiring Questcor for $5.6 billion. (*Id.* ¶ 74.) At this time, Acthar generated over 92% of Questcor's sales. (*Id.*) After purchasing Acthar, Mallinckrodt continued to substantially increase its price. (*Id.* ¶¶ 75-76.) By July 2019, Acthar retailed for over $40,000 per five milliliter vial. (*Id.* ¶ 82.) This made Acthar the single most expensive drug reimbursed by Medicare and Medicaid. (*Id.* ¶¶ 78-81.)

C. The Correct Base Date Average Manufacturer Price for Acthar

The price of Acthar on a given date is significant because it determines the amount of rebate owed by Mallinckrodt under the Medicaid Drug Rebate Program ("MDRP"). (*Id.* ¶¶ 83-84.) The MDRP requires manufacturers to pay rebates in return for Medicaid guaranteeing coverage for their drugs. (*Id.* ¶¶ 84-86.) The Centers for Medicare and Medicaid Services ("CMS"), which runs the MDRP, requires manufacturers to submit the base date average manufacturer price ("AMP") for drugs so that CMS can calculate the rebates owed by the manufacturer. (*Id.* ¶ 87.) The rebate at issue is the difference, if any, between the average AMP for the current quarter and the "base date AMP," which is the inflation-adjusted AMP of a drug. (*Id.* ¶ 90.) Federal regulations require setting the AMP as the date that the FDA approves a drug for sale and marketing, unless the drug, like Acthar, was approved before a certain date in 1990, in which case 1990 is the AMP; Acthar's AMP is thus 1990. (*Id.* ¶¶ 89-93; *see also* Pl.'s Opp'n Br. 5 n.2, ECF No. 84.) A drug's AMP is critical to calculating the MDRP rebate: the lower a drug's AMP, the higher the MDRP rebate owed as that drug's price increases over time. (Am. Compl. ¶¶ 88-96.)

When the FDA approves a drug, it assigns a unique NDA that remains with the drug for its lifetime. (*Id.* ¶¶ 97-98.) If the manufacturer of an approved drug subsequently requests to have an additional indication added to the drug's label through an sNDA, the FDA assigns a temporary "Type 6 NDA" for administrative purposes that closes upon approval of the sNDA (so the original NDA continues to apply to the drug). (*Id.* ¶ 99.) In other words, approval of an additional indication is not a new drug approval and is irrelevant to a drug's AMP. (*Id.* ¶¶ 89-97.)

D. The Improper Obtaining of Acthar's 2013 AMP

When Questcor sought to add infantile spasms to Acthar's label in 2006, the FDA assigned a temporary Type 6 NDA for the sNDA, which was NDA 022432. (*Id.* ¶103.) After approving the addition of infantile spasms in 2010, the FDA instructed Questcor to continue using the original NDA. (*Id.* ¶ 104.) On May 3, 2011, Questcor acknowledged that the Type 6 NDA was no longer valid—again, because it had been created only for administrative purposes. (*Id.* ¶ 105.) In March 2015, Mallinckrodt was likewise informed of this by the FDA. (*Id.* ¶ 106.)

But back in 2012, Questcor had a problem. Because Acthar had a 1990 AMP and the price of Acthar had risen much faster than the rate of inflation, by 2010, Questcor was paying the maximum MDRP rebate. (*Id.* ¶ 107.) Questcor realized that Acthar's obtaining of a later base date AMP (later than 1990) could save over $60 million a year in MDRP rebates. (*Id.* ¶ 113.)

In 2012, Questcor petitioned CMS to reset Acthar's AMP on the misleading premise that the approval of the infantile spasms indication resulted in a new NDA number—the temporary Type 6 NDA—being permanently assigned to Acthar. (*Id.* ¶¶ 108-09.) Questcor never informed CMS that the Type 6 NDA ceased upon approval of the sNDA and that the FDA had instructed Questcor not to use the Type 6 NDA. (*Id.* ¶ 109.)

On August 6, 2012, CMS approved setting a new AMP for Acthar because it was "approved under a different [NDA] from the original product." (*Id.* ¶ 111; *see also Mallinckrodt ARD LLC v. Verma*, 444 F. Supp. 3d 150, 164-66 (D.D.C. 2020) ("CMS Litigation") ("As the Court has repeatedly observed, CMS's 2012 letter approving Questcor's request to set a new base date AMP for Acthar indicates that the approval was premised on CMS's erroneous belief that a 'drug product' was approved under [Type 6] NDA number 022432 and . . . was different from the 'drug product' approved under [the original] NDA number.").) In January 2013, Questcor reported

a new base date AMP for Acthar and began paying rebates on Acthar as if it had first marketed the drug in 2013 instead of 1990 (and despite Acthar's price increasing drastically since 1990). (*Id.* ¶ 112.) So began the alleged underpaying of rebates.

CMS, however, was not so easily fooled. Quickly realizing that Acthar's new AMP was incorrect, CMS contacted a Questcor executive in May 2013 to request that Questcor reset Acthar's AMP back to 1990 because Acthar's NDA had never changed from the original NDA. (*Id.* ¶ 114.) Questcor failed to comply. (*Id.*)

E. Defendants Knew That Mallinckrodt Was Using the Wrong AMP for Acthar to Underpay MDRP Rebates

How does any of this supposed "Rebategate" scheme by Questcor relate to Defendants? Plaintiff alleges Defendants' knowledge in several different ways. To begin, Trudeau (Mallinckrodt's CEO), Harbaugh (former CFO), Kegler (former interim CFO), Schaefer (Principal Accounting Officer ("PAO")), Russell (Chairman of the Mallinckrodt board of directors ("Board") and member of the Board's Audit Committee), Booth (former Chairman of the Board and member of the Audit Committee) and Reed (Chairwoman of the Audit Committee) directly participated in the comprehensive due diligence activities undertaken in acquiring Questcor. (*Id.* ¶ 115.) Specifically, between January and April 2014, the Audit Committee and Mallinckrodt's management repeatedly met to discuss the due diligence on Acthar (*Id.* ¶¶ 116-21), which included Acthar's MDRP rebates. (*Id.* ¶¶ 122-23.)

Meanwhile, CMS corresponded with the FDA throughout 2014 and 2015 to ascertain the correct AMP for Acthar. *Mallinckrodt*, 444 F. Supp. 3d at 164-66. In late 2015, the FDA confirmed that the original NDA for Acthar (008372) still applied—not the temporary Type 6 NDA. *Id.* Armed with the FDA's confirmation, on April 13, 2016, CMS contacted Kay Forshee ("Forshee"), Mallinckrodt's former Senior Manager of Government Reporting who oversaw Mallinckrodt's

MDRP reporting, to demand that Mallinckrodt revert to using the 1990 AMP for Acthar and repay the avoided rebates from 2013 to 2016. (*Id.* ¶¶ 49, 124-25.)

In response, Schaefer directed her team in 2016 to calculate the scope of Mallinckrodt's MDRP rebate liability. (*Id.* ¶ 128.) James Landolt ("Landolt"), Mallinckrodt's former Director of Internal Controls who reported directly to Schaefer until July 2017 (*id.* ¶ 49) stated that Mallinckrodt "knowingly paid the [MDRP] less than it owes in rebates for Acthar" since August 2014 and owed $200 million in rebates as of April 2016. (*Id.* ¶¶ 126-28.)[4] Forshee, who testified as part of the DOJ's investigation into Landolt's *qui tam* claims, admits that Mallinckrodt's regulatory department agreed with CMS in April 2016 that Acthar's AMP was wrong because its NDA never changed. (*Id.* ¶¶ 129-32.)

On June 2, 2016, CMS reiterated to Landolt and Forshee that Mallinckrodt must revert to using the 1990 AMP for Acthar. (*Id.* ¶ 133.) This prompted Schaefer, Forshee, and Landolt to meet and discuss "CMS Notification – Acthar Baseline AMP." (*Id.* ¶135.) Two weeks later, Forshee sent Schaefer an analysis showing that Mallinckrodt owed $258 million in retroactive rebates at that time, which Schaefer acknowledged was a "significantly material" liability. (*Id.* ¶¶ 136-140.)

In March 2018, the Audit Committee received a presentation from Schaefer stating that CMS informed Mallinckrodt that "Acthar had to revert to the [b]ase AMP established in 1990" and that this had resulted in "liability [that] would be retroactive to 2010 through" the present, and "would be in the hundreds of millions of dollars." (*Id.* ¶ 142.) This language was included in several other presentations in 2018, during which time the Audit Committee met thirteen times,

[4] Landolt is the relator in *Landolt v. Mallinckrodt ARD LLC*, No. 1:18-1193 (D. Mass.). Landolt's allegations were fully corroborated by an independent investigation of the United States Department of Justice ("DOJ"), which intervened in Landolt's *qui tam* case on March 3, 2020 and concluded (based on numerous e-mail messages and documents) that Mallinckrodt had knowingly underpaid CMS.) (*Id.* ¶¶ 129, 163-64.)

more than any other Board committee. (*Id.* ¶¶ 143-44.) Carter, who joined the Board and Audit Committee in May 2018, necessarily was apprised of this information. (*Id.* ¶ 39.) Thus, the Audit Committee at this point in time included Defendants Booth, Russell, Reed, and Carter.

On November 6, 2018, CMS contacted Schaefer to reiterate that Mallinckrodt was using the wrong AMP for Acthar. (*Id.* ¶ 146.) Casey, who joined Mallinckrodt in February 2018 (*id.* ¶ 40), and Mallinckrodt's Chief Compliance Officer ("CCO"), who reported directly to Trudeau (*id.* ¶ 147), and Schaefer each met once with CMS during the early months of 2019. (*Id.* ¶¶ 148, 150.) At several points in March 2019, CMS then reiterated to Schaefer and Casey that Mallinckrodt was improperly avoiding the correct MDRP rebates, as Mallinckrodt had been consistently told since 2016. (*Id.* ¶¶ 151-52.)

Defendants contend that CMS's specific communication on March 27, 2019 represented the "final decision" of CMS, who had been "confused" beforehand. (Defs.' Moving Br. 7, ECF No. 79-1.) Nonetheless, Mallinckrodt continued using the 2013 AMP. (Am Compl. ¶ 154.) On May 10, 2019, CMS again reiterated these points in correspondence to Schaefer explaining, among other things, that if Mallinckrodt did not change the AMP, Acthar would be listed as "out of compliance," with possible referral of the matter to DOJ. (Am. Compl. ¶ 155; Defs.' Moving Br. 7.) Reasons, who became Mallinckrodt's CFO on March 18, 2019, was necessarily apprised of these facts. (Am. Compl. ¶ 34.)

F. The Fallout

On May 20, 2019, Mallinckrodt sued for injunctive relief to stop CMS from reverting the AMP for Acthar back to 1990. (*Id.* ¶ 156; *see generally Mallinckrodt*, 444 F. Supp. 3d at 150.) Analysts emphasized that investors were never previously told of a dispute between Mallinckrodt and CMS regarding Acthar. (Am. Compl. ¶¶ 159-61.) On March 13, 2020, the Hon. Thomas F.

Hogan, U.S.D.J., granted CMS's motion for summary judgment in the CMS Litigation. (*Id.* ¶¶ 166-67.) On March 16, 2020, Mallinckrodt acknowledged that it now owed $650 million to CMS and that changing Acthar's AMP would reduce annual Acthar net sales by $100 million in perpetuity. (*Id.* ¶¶ 168-69.) On October 12, 2020, due to the CMS liability (*Id.* ¶ 182), Mallinckrodt filed for bankruptcy. (Pl.'s Opp'n Br., Ex. 1.) In connection therewith, Mallinckrodt agreed to: (i) settle the CMS Litigation for $260 million; (ii) revert to using the 1990 AMP for Acthar; and (iii) stay its then-pending appeal of Judge Hogan's summary judgment ruling. (*Id.* at 5.) The settlement of the CMS Litigation in March 2022 resulted in the dismissal of the CMS Litigation appeal in July 2022. (July 28, 2022 Ltr. 1, ECF No. 102.)

G. Defendants' Knowledge in May 2019 That Mallinckrodt Could Not Achieve Its Fiscal Year 2019 Guidance for Acthar

On May 7, 2019, Trudeau reaffirmed Mallinckrodt's 2019 fiscal year guidance ("Acthar FY19 Guidance") for Acthar net sales in excess of $1 billion. (Am. Compl. ¶¶ 184-85, 246.) Likewise, in announcing the CMS Litigation soon after, the Company reiterated the Acthar FY19 Guidance. (*Id.* ¶ 247.) Defendants concede that by March 27, 2019, CMS required Mallinckrodt to change Acthar's AMP. (*Id.* ¶ 176, Defs.' Moving Br. 7, 27.) On August 6, 2019, Mallinckrodt disclosed in its financials that due to the "uncertainty" of the CMS Litigation, Mallinckrodt "now believes Acthar [] net sales for 2019 are unlikely to exceed $1 billion." (Am. Compl. ¶ 189.) Thereafter, Mallinckrodt declined to provide fiscal year 2020 guidance for Acthar for the same reason. (*Id.* ¶¶ 181, 191.)

H. Mallinckrodt Sought to Obtain Additional Indications for Acthar Because of the Impending AMP Liability

Despite Acthar having been approved since 1952 to treat numerous diseases, Mallinckrodt pursued multiple clinical drug trials during the Class Period to expand the number of indications

for Acthar to treat, in part to create alternative revenue streams in light of the significant CMS liability that the Company faced. (*Id.* ¶ 192.)

I. Defendants Were Negotiating a Settlement of the *Strunck* Litigation in March 2019

According to a *qui tam* lawsuit brought by a former Mallinckrodt employee, Acthar was illegally marketed off-label by Mallinckrodt (the "*Strunck* Litigation"). (*Id.* ¶¶ 195-200.) The DOJ moved to intervene in the *Strunck* Litigation on March 7, 2019. (*Id.* ¶ 201.) Investors learned about the *Strunck* Litigation on April 30, 2019. (*Id.* ¶ 203.) That same day, Mallinckrodt issued a press release admitting that it had "been in advanced settlement talks with the government over the past several months," *i.e.,* around February 2019 or earlier, to resolve the *Strunck* Litigation. (*Id.* ¶¶ 206-07.) In other words, Defendants were actively negotiating a resolution when the Company's Form 10-K was filed on February 26, 2019 (the "2018 Form 10-K") without disclosing that the *Strunck* Litigation was pending. (*Id.*) The *Strunck* Litigation settled for $15.4 million in September 2019. (*Id.* ¶¶ 208-11.)

J. The Instant Motion

Plaintiff contends that Defendants' knowledge or reckless disregard of the improper avoidance of rebates pertaining to Acthar led to false and misleading statements about (1) Acthar's rebates, (2) the Acthar FY19 Guidance, (3) Mallinckrodt's Class Period Forms 10-K and 10-Q ("Class Period Financial Statements"), and (4) Mallinckrodt's efforts to find alternative revenue streams for Acthar. (Pl.'s Opp'n Br. 2, ECF No. 84.) Plaintiff further contends that Defendants also made incomplete disclosures regarding the *Strunck* Litigation. (Pl.'s Opp'n Br. 2.) Defendants move to dismiss both of Plaintiff's counts under Federal Rules of Civil Procedure 9(b) and 12(b)(6) and pursuant to the PSLRA, initially filing their brief in October 2020. (*See generally* Defs.' Moving Br.) One month later, Plaintiff opposed. (*See generally* Pl.'s Opp'n Br.) Shortly thereafter,

the Court stayed all proceedings in this action pending resolution of bankruptcy proceedings involving Mallinckrodt. (ECF No. 89.) Following the Court's reinstation of the litigation in this case in March 2022 (ECF No. 93), Defendants filed their reply (ECF No. 95).

II. LEGAL STANDARDS

A. Standards for Rule 12(b)(6) Motion to Dismiss

Under Rule 8 of the Federal Rules of Civil Procedure, a pleading is sufficient so long as it includes "a short and plain statement of the claim showing that the pleader is entitled to relief" and provides the defendant with "fair notice of what the . . . the claim is and the grounds upon which it rests."[5] *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (internal citation omitted). In considering a Rule 12(b)(6) motion to dismiss, the court accepts as true all of the facts in the complaint and draws all reasonable inferences in favor of the non-moving party. *Phillips*, 515 F.3d at 231. Moreover, dismissal is inappropriate even where "it appears unlikely that the plaintiff can prove those facts or will ultimately prevail on the merits." *Id.*

The facts alleged, however, must be "more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Twombly*, 550 U.S. at 555. That is, the allegations in the complaint "must be enough to raise a right to relief above the speculative level." *Id.* Accordingly, a complaint will survive a motion to dismiss if it provides a sufficient factual basis such that it states a facially plausible claim for relief. *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009).

[5] Hereafter, all references to "Rule" or "Rules" refer to the Federal Rules of Civil Procedure.

B. Standards for Securities Fraud

Section 10(b) of the Exchange Act prohibits the "use or employ, in connection with the purchase or sale of any security . . . [of] any manipulative or deceptive device or contrivance in contravention of such rules and regulations as the [SEC] may prescribe as necessary or appropriate in the public interest or for the protection of investors." 15 U.S.C. § 78j(b). SEC Rule 10b–5, which implements § 10(b), makes it unlawful:

> (a) To employ any device, scheme, or artifice to defraud,
> (b) To make any untrue statement of a material fact or to omit to state a material fact necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading, or
> (c) To engage in any act, practice, or course of business which operates or would operate as a fraud or deceit upon any person, in connection with the purchase or sale of any security.

17 C.F.R. § 240.10b–5. To state a claim under § 10(b) and SEC Rule 10b–5, a plaintiff must allege: "(1) a material misrepresentation or omission by the defendant; (2) scienter; (3) a connection between the misrepresentations or omission and the purchase or sale of a security; (4) reliance upon the misrepresentation or omission; (5) economic loss; (6) and loss causation." *Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 37-38 (2011) (quotation marks and citation omitted). "A corporation is liable for statements by employees who have apparent authority to make them." *Inst. Invs. Grp. v. Avaya, Inc.*, 564 F.3d 242, 252 (3d Cir. 2009) (internal quotation and citations omitted).

Section 20(a) of the Exchange Act creates a cause of action against individuals who exercise control over a "controlled person," including a corporation, that has committed a violation of Section 10(b). 15 U.S.C. § 78t(a); *In re Suprema Specialties, Inc. Sec. Litig.*, 438 F.3d 256, 284 (3d Cir. 2006). Accordingly, liability under Section 20(a) is derivative of an underlying violation of Section 10(b) by the controlled person. *Avaya, Inc.*, 564 F.3d at 252; *In re Alpharma Inc. Sec.*

Litig., 372 F.3d 137, 153 (3d Cir. 2004) ("[P]laintiffs must prove not only that one person controlled another person, but also that the 'controlled person' is liable under the Act.") (internal quotation marks omitted)

Independent of the standard applicable to Rule 12(b)(6) motions, Rule 9(b) requires that "[i]n all averments of fraud or mistake, the circumstances constituting fraud or mistake shall be stated with particularity"—a particularity requirement that "has been rigorously applied in securities fraud cases." *Cal. Pub. Emps.' Ret. Sys. v. Chubb Corp.*, 394 F.3d 126, 144 (3d Cir. 2004) (citing *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1417 (3d Cir. 1997)). As such, plaintiffs asserting securities fraud claims must specify "the who, what, when, where, and how: the first paragraph of any newspaper story." *In re Advanta Corp. Sec. Litig.*, 180 F.3d 525, 534 (3d Cir. 1999) (quoting *DiLeo v. Ernst & Young*, 901 F.2d 624, 627 (7th Cir. 1990)). "Although Rule 9(b) falls short of requiring every material detail of the fraud such as date, location, and time, plaintiffs must use 'alternative means of injecting precision and some measure of substantiation into their allegations of fraud.'" *In re Rockefeller Ctr. Props., Inc. Sec. Litig.*, 311 F.3d 198, 216 (3d Cir. 2002) (quoting *In re Nice Systems, Ltd. Sec. Litig.*, 135 F. Supp. 2d 551, 577 (D.N.J. 2001)). Rule 9(b) governs Plaintiff's Exchange Act claims. *Cal. Pub. Emps.' Ret. Sys.*, 394 F.3d at 144.

In addition to satisfying Rule 9(b), plaintiffs alleging securities fraud pursuant to the Exchange Act must also comply with the heightened pleading requirements of the PSLRA. The PSLRA "imposes another layer of factual particularity to allegations of securities fraud." *In re Rockefeller*, 311 F.3d at 217. To allege fraud under the PSLRA, the plaintiff must "state with particularity both the facts constituting the alleged violation, and the facts evidencing scienter, i.e., the defendant's intention 'to deceive, manipulate, or defraud.'" *Tellabs, Inc. v. Makor Issues &*

Rights, Ltd., 551 U.S. 308, 313, 321 (2007) (quoting *Ernst & Ernst v. Hochfelder*, 425 U.S. 185, 194, and n.12. (1976), and citing 15 U.S.C. § 78u–4(b)(1), (2)). In order to satisfy this particularity requirement, the plaintiff must plead "facts giving rise to a strong inference that the defendant acted with the required state of mind." 15 U.S.C. § 78u–4(b)(2)(A). A strong inference exists "only if a reasonable person would deem the inference of scienter cogent and at least as compelling as any opposing inference one could draw from the facts alleged." *Tellabs, Inc.*, 551 U.S. at 324.

III. DISCUSSION

Defendants' Motion rests on several grounds: that Plaintiff has failed to state a claim under either Section 10(b) or Section 20(a). The Court addresses each contention in turn.

A. Plaintiff Has Stated a Claim Under Section 10(b)

Defendants contend that Plaintiff has failed to state a claim under Section 10(b) of the Exchange Act. In moving to dismiss the Section 10(b) claim, Defendants only contest scienter and whether Defendants made a materially false or misleading statement or omission. (*See generally* Defs.' Moving Br.)

1. Plaintiff has adequately alleged a strong inference of scienter.

First, Defendants argue that Plaintiff has failed to allege a strong inference of scienter. (Defs.' Moving Br. 11.) Scienter is as an "intent 'to deceive, manipulate or defraud.'" *In re Elecs. for Imaging, Inc. Sec. Litig.*, 2019 WL 397981, at *6 (D.N.J. Jan. 31, 2019) (quoting *Tellabs, Inc.*, 551 U.S. at 313). To allege scienter, Plaintiff must plead "with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." *Id.* A "strong" inference is not "merely reasonable or permissible," it must be "cogent and at least as compelling as any opposing inference one could draw from the facts alleged." *Fain v. USA Techs., Inc.*, 707 F. App'x 91, 95 (3d Cir. 2017) (quoting *Tellabs, Inc.*, 551 U.S. at 324). Scienter can be established through knowledge or recklessness. *See Fain*, 707 F. App'x at 96. The Third Circuit has "explicitly

approved of . . . assess[ing] . . . scienter allegations individually," and then "ultimately consider[ing] the allegations as a whole." *In re Hertz Global Holdings, Inc.*, 905 3d 106, 115 (3d Cir. 2018) (citation omitted). The relevant inquiry for recklessness is whether defendants "should have known that they were misrepresenting material facts related to the corporation[,]" *i.e.*, when defendants had "knowledge of facts or access to information contradicting their public statements." *In re Campbell Soup Co. Sec. Litig.*, 145 F. Supp. 2d 574, 599 (D.N.J. 2001).

In her opposition, Plaintiff contends that the Amended Complaint adequately pleads scienter and divides the scienter inquiry by category of the misleading statement or omission. (*See* Pl.'s Opp'n Br. 29-38.) As for the Class Period Financial Statements, Plaintiff alleges: (1) the direct knowledge of Schaefer, which she acquired from CMS communications, in 2016 that Mallinckrodt was underpaying Acthar rebates—and Schaefer's subsequent direct conveyance of that information to the Audit Committee (Booth, Russell, Reed, and Carter) in 2018; (2) the participation in due diligence, undertaken in acquiring Questcor, of Trudeau, Harbaugh, Kegler, Schaefer, Russell, Booth, and Reed; (3) all of Defendants' senior roles and general access to information pertaining to the correct AMP for Acthar, and by way of the Core Operations Doctrine and the sheer magnitude of the over $600 million in avoided rebates;[6] (4) Generally Accepted Accounting Principles ("GAAP") violations; (5) the meeting between Casey and CMS in January

[6] One argument that Plaintiff asserts is that the Core Operations Doctrine supports scienter because "Acthar was Mallinckrodt's most important drug during the Class Period, annually contributing over one-third of the [c]ompany's net sales." (Pl.'s Opp'n Br. 32-33.) Defendants contend that the Core Operations Doctrine "is no substitute for scienter; where it is invoked, it must be accompanied by particularized allegations showing that Defendants knew the statement was false"; Defendants similarly contest Plaintiff's reliance on the magnitude of potential liability. (Defs.' Reply Br. 5-6, ECF No. 95.) Here, the Court reaches its decision based upon the totality of Plaintiff's allegations. *See In re Valeant Pharms. Int'l, Inc. Sec. Litig.*, 2017 WL 1658822, at 8 n.15 (not reaching defendants' argument pertaining to the viability of the Core Operations Doctrine in light of finding scienter due to the totality of plaintiffs' allegations).

2019 to discuss CMS's repeated position that Mallinckrodt was using the wrong AMP for Acthar; and (7) the fact that Reasons was appraised of CMS's position upon becoming Mallinckrodt's CFO in March 2019. (*See* Pl.'s Opp'n Br. 9, 30-37.) The Court analyzes several of these contentions in turn.

To begin, Plaintiff alleges that Defendants' due diligence in acquiring Questcor is a source of scienter. It is true, as Defendants contend, that "rote allegations that the [] defendants must have had knowledge of the 'true facts' based upon their supervision of the due diligence . . . runs afoul of the [PSLRA]." *Cal. Pub. Emps.' Ret. Sys. v. Chubb Corp.*, No. 00-4285, 2002 WL 33934282, at *23 (D.N.J. June 26, 2002). Similarly, "[w]here plaintiffs contend defendants had access to contrary facts, they must specifically identify the reports or statements containing this information." *Id.* (quoting *Novak v. Kasaks*, 216 F.3d 300, 309 (2d Cir.), *cert. denied*, 531 U.S. 1012 (2000)). But here, Plaintiff does allege particularized facts. For example, Plaintiff points to specific proxy statements that signal the "extensive due diligence" of Trudeau, Harbaugh, Kegler, Schaefer, Russell, Booth, and Reed throughout 2014, as well as a conversation in which the then-head of Mallinckrodt's Specialty Brands business stated during an investor earnings call that the due diligence included "the way the product is positioned for reimbursement." (Am. Compl. ¶¶ 119, 123.) And while these statements alone may not be enough to demonstrate that these individuals undoubtedly knew they were using the wrong base date AMP for Acthar, they do suggest that at the very least, these individual Defendants had access to information to ascertain the correct AMP for Acthar, which can support a finding of recklessness. *See In re Valeant Pharms. Int'l, Inc. Sec. Litig.*, No. 157-658, 2017 WL 1658822, at *8 (D.N.J. Apr. 28, 2017) (finding scienter where allegations included, in part, individual defendants' due diligence related to acquiring an option to purchase). The Amended Complaint also specifically alleges the

information that these individual Defendants could have used to ascertain the correct AMP, including: (1) FDA's communications to Questcor in 2010 to not use the Type 6 NDA, which could have been uncovered through due diligence (Am. Compl. ¶¶ 103-04); and (2) CMS's statement to Questcor in May 2013 that Acthar's AMP was incorrect and required revision (*Id.* ¶114; *see also Mallinckrodt*, 444 F. Supp. 3d at 164 ("About nine months later, on May 28, 2013, a CMS official emailed Questcor's Director of Business Analytics and Evaluation to request that Questcor correct Acthar's base date AMP.").)

Next, the issue of the Acthar FY19 Guidance statements arises. Plaintiff contends that Defendants made the challenged Acthar FY19 Guidance statements about Mallinckrodt's ability to achieve its net sales for Acthar in May 2019 despite knowledge to the contrary. (Pl.'s Opp'n Br. 37.) Defendants contend that Plaintiff fails to allege that forward-looking statements in the Acthar FY19 Guidance were made with actual knowledge. (Defs.' Moving Br. 21.) Yet Defendants concede that by March 2019, they knew that CMS required Acthar to revert to a 1990 AMP. (Defs.' Moving Br. 7 ("On March 27, 2019, CMS informed Mallinckrodt it had reached its 'final decision.'").) The Court thus finds that Plaintiff adequately alleges that part of this guidance referred to present matters for which there is no safe harbor, such as Trudeau's statement of confidence in Acthar's net sales in May 2019 (Am. Compl. ¶ 246) and further alleges specific facts which were known to or recklessly disregarded by Defendants during this time. (Am. Compl. ¶ 248.) *See In re Celgene Corp. Sec. Litig.*, No. 18-4772, 2019 WL 6909463, at *14 (D.N.J. Dec. 19, 2019) (statement that company was "on track" to meet its guidance was not forward-looking as it pertained "to Celgene's current position"); *Emps. Ret. Sys. of the P.R. Elec. Power Auth. v. Conduent Inc.*, 2020 WL 3026536, at *4-5 (D.N.J. June 5, 2020) (statement that company's strategic transformation was "progressing well" was actionable because it contained a present

component). Again, Defendants were undoubtedly informed by CMS in March 2019 that Acthar had to revert to using the 1990 AMP, and they concede as much. (*See* Defs.' Moving Br. 7.)

As further support of scienter, Plaintiff points to the *Strunck* Litigation omissions. As discussed earlier, Plaintiff alleges that Mallinckrodt's April 30, 2019 press release issued in response to the public disclosure of the *Strunck* Litigation implicitly admits that Defendants were actively negotiating a settlement before the 2018 Form 10-K was filed—yet the 2018 Form 10-K failed to disclose this information. (Am. Compl. ¶¶ 206-07.) This fact supports Defendants' scienter for these alleged omissions. *See, e.g., Avaya, Inc.*, 564 F.3d at 269 (explaining that "the most powerful evidence of scienter is the content and context of [the] statements").

Finally, the parties raise the issue of GAAP violations, which is an issue of little significance since the Court has already found scienter.[7] *See In re Perrigo Co. PLC Sec. Litig.*, No. 19-70, 2021 WL 517441, at *3 (S.D.N.Y. Feb. 10, 2021) ("An allegation of a GAAP violation is insufficient to state a securities fraud claim . . . ."). In any event, the Court finds that this issue, too, weighs in favor of Defendants' knowing or reckless violation of securities laws. Plaintiff alleges that Defendants knowingly or recklessly caused the Company to issue financial statements during the Class Period on Forms 10-K and 10-Q in violation of GAAP. (Am. Compl. ¶¶ 10, 181, 216-17.) The GAAP violation at issue is Accounting Standards Codification Topic 450 ("ASC 450"). ASC 450 requires company disclosure when a loss is "probable" or "reasonably possible." *In re Hertz Glob. Holdings, Inc. Sec. Litig.*, No. 13-7050, 2017 WL 1536223, at *11 (D.N.J. Apr. 27, 2017), *aff'd* 905 F.3d 106 (3d Cir. 2018). Defendants argue that the complex and subjective

[7] GAAP are principles issued by the Financial Accounting Standards Board for use by accountants in preparing financial statements, which include broad guidelines as well as detailed practices and procedures. *Underland v. Alter*, No.10-3621, 2011 WL 4017908, at *6 (E.D. Pa. Sept. 9, 2011) (internal quotation marks omitted).

nature of this rule weighs in favor of finding that the claims at issue here are opinions, rather than facts, and that Plaintiff fails to plead particularized facts meeting the standard for opinion liability. (Defs.' Moving Br. 14-15.)[8] Here, the Court agrees with Defendants that statements about GAAP compliance and ASC 450 are statements about opinions. *See Hertz*, 2017 WL 1536223, at *11 (statements about GAAP compliance and ASC 450 are "opinions"). Plaintiff does not allege sufficient facts demonstrating that Defendants "bypass[ed] a methodology or metric" such that the accounting claims are misstatements of facts, but rather, alleges that Defendants incorrectly applied ASC 450. (*See id.*; *cf.* Am Compl. ¶¶ 222-29.) The nexus of the dispute, thus, is which standard to apply to determine whether the opinions are actionable. Defendants contend that the *Edinburgh* standard applies, under which an opinion is "only actionable under the securities laws if [it is] not honestly believed and lack[s] a reasonable basis." *City of Edinburgh Council v. Pfizer, Inc.*, 754 F.3d 159, 170 (3d Cir. 2014). Plaintiff, on the other hand, contends that the *Omnicare* standard applies, under which a statement of opinion is actionable if: (1) the opinion is not sincerely held by the speaker; (2) the opinion contains an embedded or "underlying" fact that is false; or (3) the opinion omits a fact that renders it misleading to an ordinary investor. *Omnicare Inc. v. Laborers Dist. Council Const. Indus. Pen. Fund*, 575 U.S. 175, 184-85, 189 (2015). The Court need not resolve this dispute at this time, however, because Plaintiff satisfies its burden under either standard. Plaintiff alleges that Defendants knew by at least May 3, 2016 (when

[8] Defendants aver in their reply that Plaintiff's claim here fails to the extent it challenges the statement that financials complied with GAAP, because Plaintiff does not dispute Defendants' own contention that this is a non-actionable opinion. (Defs.' Reply Br. 2, ECF No. 95.) But Plaintiff does dispute the characterization that ASC 450 determinations are always opinions, and ASC is the source of authoritative GAAP to be applied by nongovernmental entities. (Am. Compl. ¶ 222; Pl.'s Opp'n Br. 21 ("Courts routinely find that violating accounting standards like ASC 450 constitutes actionable misstatements of facts (and not opinions) when it is alleged (as here) that defendants failed to consider all material factors (past and present information) under GAAP." (internal quotation marks omitted)).) Thus, the Court finds this point by Defendants unavailing.

Defendants filed a Form 10-Q for the fiscal quarter ending that March and when this Class Period begins) the possibility of Mallinckrodt underpaying MDRP rebates for Acthar by using the wrong base date AMP; indeed, as explained above, Plaintiff alleges that CMS repeatedly told Defendants (and specifically, Schaefer) during the Class Period that Acthar was using the wrong AMP. (Am. Compl. ¶¶ 106, 109-10, 114, 116-23, 125-40, 146-55, 162, 167; Pl.'s Opp'n Br. 20.) Yet Plaintiff alleges that despite this knowledge, and continued admonitions by CMS, Mallinckrodt continued to use the wrong base date AMP. (Am. Compl. ¶¶ 133-40, 146-55, 228.) At this juncture, the Court finds that Plaintiff has alleged sufficient facts creating a plausible inference that Defendants did not sincerely believe, nor did they have a reasonable basis to believe, that their financial statements complied with ASC 450, and that they, accordingly, did not have a reason to disclose a possible rebate liability before August 2019. The Court finds that the GAAP violations, when considered holistically with the other allegations of the Amended Complaint, establish scienter.

Considering Defendants' contentions, Defendants "primarily respond by dividing [Plaintiff's] allegations into discrete parts and arguing that each part fails to give rise to sufficient scienter." (*In re Valeant Pharms. Int'l, Inc. Sec. Litig.*, No. 15-7658, 2017 WL 1658822, at *10 (D.N.J. Apr. 28, 2017); *see generally* Defs.' Moving Br.)[9] For the purposes of evaluating "plausible, nonculpable explanations for [Defendants'] conduct," the Court considers Defendants' argument that "the more plausible inference is that Defendants did not act with fraudulent intent."

[9] Defendants raise the point that Plaintiff failed to allege a motive to defraud shareholders, which cuts against an inference of scienter. (Defs.' Moving Br. 11.) Plaintiff concedes that it "does not rely on motive to plead scienter." (Pl.'s Opp'n Br. 29 n.15.) While an absence of allegations of a motive to defraud "raises a compelling inference against scienter," "motive is neither sufficient nor necessary to finding scienter." *Roofer's Pens. Fund v. Papa*, No. 16-2805, 2018 WL 3601229, at *17 (D.N.J. July 27, 2018). The Court, accordingly, considers the absence of motive in deciding whether scienter exists, but finds it not dispositive to the Court's determination of the element.

(Defs.' Moving Br. 22 (citing *Tellabs, Inc.*, 551 U.S. at 324).) The Defendants' lone arguments in support of their alternative explanation, in light of the totality of Plaintiff's allegations, are that: (1) "information Mallinckrodt learned during due diligence confirmed their belief in Questcor's position, and renewed its desire to consummate the $5.6 billion transaction"; (2) "each [i]ndividual Defendant (except Kegler) *increased* their stock holdings and *none* of them sold stock" (emphasis in original); and (3) "[i]t is also more plausible that Defendants negotiated with CMS for over three years—and proactively sued CMS—because they honestly believed the Company was using the correct base date AMP." (Defs.' Moving Br. 22-24.) Because it is plausible that Defendants acted with reckless disregard to the improper avoidance of rebates pertaining to Acthar, the mere fact that Defendants generally did not sell stock, for example, is insufficient to render Plaintiff's allegations deficient. *See Avaya, Inc.*, 564 F.3d at 270 (explaining that allowing recklessness to serve as a sufficient basis for liability "promotes the policy objective[ ] of discouraging deliberate ignorance"). The Court finds that "[w]hen all the allegations are accepted as true and taken collectively, . . . a reasonable person [would] deem the inference of scienter at least as strong as" Defendants' alternative theory. *Tellabs, Inc.*, 551 U.S. at 326.

The Court thus finds Defendants' remaining arguments unavailing. Because the Court is allowed to consider the totality of Plaintiff's Amended Complaint, the Court rejects, for example, Defendants' argument that Plaintiff has "lump[ed] [Defendants] together and allege[d] a collective state of mind." (Defs.' Moving Br. 21.) Indeed, Plaintiff has alleged a source of scienter for each individual Defendant, in conjunction with alleging collective scienter for certain actions (*i.e.* for the Core Operations Doctrine and magnitude inferences) (Pl.'s Opp'n Br. 33 n.18) and alleging the specific statements or omissions for which each individual Defendant is allegedly responsible (*see, e.g.*, Am. Compl. ¶ 35 ("Defendant Schaefer signed each of the Company's Forms 10-K filed

with the SEC during the Class Period."), 245 (chart tagging each individual Defendant to a specific misleading financial statement)).

It is also not lost on the Court that many of Defendants' arguments pertaining to their lack of fraudulent intent, such as their suit against CMS, stem from what Defendants contend was "CMS's confusion" and shifting of theories pertaining to Acthar's base date AMP. (Defs.' Moving Br. 7.) Yet Judge Hogan explicitly found in the CMS Litigation that "[f]rom 2016 through 2019, CMS gave [Mallinckrodt] more than ample opportunity to bring its reporting into compliance so it would not continue to accrue rebate underpayments for which it would be liable." (Am. Compl. ¶ 167; *Mallinckrodt*, 444 F. Supp. 3d at 181.)[10]

For these reasons, the Court finds that Plaintiff has sufficiently pled scienter based on the Court's holistic review of the Amended Complaint.

2. Materiality; Actionable Statements and Omissions

Defendants also contest whether Plaintiff has alleged a materially false or misleading statement or omission.[11] A misstatement or omission is material if "there is a substantial likelihood that a reasonable [investor] would consider it important in deciding how to [act]." *In re Donald J.*

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[10] Defendants contend in their reply brief that the fact "[t]hat CMS prevailed before Judge Hogan is of no import; if Mallinckrodt's position had no legal merit, Judge Hogan would not have devoted 49 pages to the disputed issue, which is now on appeal." But Mallinckrodt agreed to withdraw the CMS Litigation appeal pursuant to Mallinckrodt's March 3, 2022 settlement agreement with the DOJ, which occurred even before Defendants filed their reply on May 2, 2022 (ECF No. 95)—the appeal was dismissed on July 14, 2022. (July 28, 2022 Ltr. 1.) And Defendants appear to agree that courts may consider documents upon which the Amended Complaint cites and relies, including those filed in other related actions—Defendants even include the CMS Litigation opinion as an attachment to their Motion. (Defs.' Moving Br. 5 n.2.; Ex. 7, ECF No. 79-9.)

[11] Plaintiff contends that Defendants contest the falsity of the alleged misstatements and omissions, but not their materiality. (Pl.'s Opp'n Br. 2.) Yet Defendants specifically contend that Plaintiff "fails to[] allege Defendants made a materially false or misleading statement or omission." (Defs.' Moving Br. 24.)

Trump Casino Sec. Litig.–Taj Mahal Litig., 7 F.3d 357, 369 (3d Cir. 1993) (alterations in original) (quoting *TSC Indus., Inc. v. Northway, Inc.*, 426 U.S. 438, 449 (1976)). In other words, a misstatement or omission is material if the information "would have been viewed by the reasonable investor as having significantly altered the total mix of information available to that investor." *Oran v. Stafford*, 226 F.3d 275, 282 (3d Cir. 2000) (internal quotations and citations omitted).

Upon review of these allegations and the authorities presented by the parties, the Court finds that Plaintiff has sufficiently pled materiality. Plaintiff alleges actionable false statements and omissions pertaining to: (1) the Acthar rebates; (2) the Acthar FY19 Guidance; (3) the Class Period Financial Statements; (4) the Acthar clinical trial omissions; (5) the *Strunck* Litigation omissions; and (6) Items 103 (17 C.F.R. § 229.103), 303 (17 C.F.R. § 229.303), and 503 (17 C.F.R. §229.105) of SEC Regulation S-K ("Items").[12] (*See* Pl.'s Opp'n Br. 14-28.) While Defendants target certain portions of these particular alleged statements and omissions, Defendants fail to sufficiently address numerous alleged misstatements and omissions regarding Mallinckrodt's purported reckless practices, which a reasonable investor would have considered important. *See In re Vivendi, S.A. Sec. Litig.*, 838 F.3d 223, 250 (2d Cir. 2016) ("'The test for whether a statement is materially misleading under Section 10(b)' is not whether the statement is misleading in and of itself, but 'whether the defendants' representations, *taken together and in context*, would have misled a reasonable investor.'" (emphasis in original) (quoting *Rombach v. Chang*, 355 F.3d 164, 172 n.7 (2d Cir. 2004))). For example, as one allegation pertaining to the Acthar rebate omissions,

[12] "The SEC created specific rules governing the content of disclosures by public companies in their filings with the SEC." (Am. Compl. ¶ 207.) Items 103, 303, and 503 "required Mallinckrodt to disclose legal proceedings, known trends, events, and uncertainties, and material risks in its Class Period Forms 10-K and 10-Q." (*Id.* ¶ 15.) For specifics on what these Items entail, *see* Am. Compl. ¶¶ 297-310.

in Mallinckrodt's Form 10-K filed on February 27, 2018, Defendants stated that the increase in Acthar net sales was "driven by [favorable pricing] and lower rebate expenses." (Am. Compl. ¶ 262.) Plaintiff alleges that this statement omitted the fact that Mallinckrodt was using the wrong AMP for Acthar, yet Defendants fail to squarely address Plaintiff's argument. (Pl.'s Opp'n Br. 15.) Such an omission would be both material and actionable for failure to address the ongoing CMS communications pertaining to the improper AMP base date, and the Court finds this to be true for all the Acthar rebate omissions as a whole. *See Odeh v. Immunomedics, Inc.*, No. 18-17645, 2020 WL 4381924, at *6-7 (D.N.J. July 31, 2020) (finding actionable a failure to disclose an event that could have jeopardized FDA approval when discussing the FDA's review of a drug).

The Court has also already discussed how certain other statements, such as those pertaining to GAAP violations, Acthar FY 2019 Guidance, and the *Strunck* Litigation, establish scienter and applying the above reasoning, the Court finds them actionable. *See Kline v. First W. Gov't Sec., Inc.*, 24 F.3d 480, 490-91 (3d Cir. 1994) (finding actionable omissions when, as here, executives "elected to speak" but "failed to include . . . information that, if included, would have undermined the conclusions" made in those statements). The Court further finds that Plaintiff has pled sufficient materiality for Items 103, 303, and 503 omissions and that when considering them with other statements and omissions, they are actionable. *See, e.g., Jaroslawicz v. M&T Bank Corp.*, 962 F.3d 701, 716 (3d Cir. 2020), *cert. denied*, 141 S. Ct. 1284 (2021) ("Item 103[] does require disclosure of potential or present litigation or regulatory enforcement."). The Court only adds, in response to Defendants' argument that the Acthar FY 2019 Guidance was accompanied by cautionary language and thus, is not actionable (Defs.' Moving Br. 28) that, as discussed, Plaintiff pleads sufficient facts showing that Mallinckrodt knew that CMS had determined Mallinckrodt's failure to comply with its rebate yet continued to underpay; thus, these risks had already come to

pass. (Pl.'s Opp'n Br. 17-19.) "The Court finds that at this early stage of the litigation . . . any forward-looking statements made by Defendants regarding [the Acthar FY19 Guidance] were not accompanied by sufficient cautionary language." *In re: Enzymotec Sec. Litig.*, No. 14-556, 2015 WL 8784065, at *11 (D.N.J. Dec. 15, 2015) (rejecting cautionary language where the "risks had already come to pass").

As for the Acthar clinical trial omissions, however, the Court agrees with Defendants that they had no duty to disclose more information, as Plaintiff's theory that Mallinckrodt conducted these additional clinical trials to offset its sales reduction is "pure conjecture and not actionable." (Defs.' Moving Br. 38; *Calif. Pub. Emps. Ret. Sys.*, 394 F.3d 126 at 155 ("Generic and conclusory allegations based upon rumor or conjecture are undisputedly insufficient" to satisfy the PSRLA).)

For the reasons set forth above, the Court finds that Defendants' representations on the above statements and omissions, with the exclusion of the alleged Acthar clinical trial omissions, support a finding of materiality and falsity. Accordingly, the Court finds that the Amended Complaint sufficiently pleads actionable statements and omissions and that thus, Plaintiff has stated a claim under Section 10(b).

B. Plaintiff Has Stated a Claim Under Section 20(a)

Defendants finally contend that Plaintiff has failed to state a "control person" claim under Section 20(a) of the Exchange Act. (Defs.' Moving Br. 40.) Having found that Plaintiff sufficiently alleges a Section 10(b) claim, the Court turns to whether Plaintiff has sufficiently alleged control and finds that Plaintiff has done so. Plaintiff adequately alleges a primary violation by each individual Defendant, sets forth the specific allegations of misstatements and omissions, and asserts a primary violation of Section 10(b) against Mallinckrodt. *See Zhengyu He v. China Zenix Auto Int'l Ltd.*, No. 18-15530, 2020 WL 3169506, at *13 (D.N.J. June 12, 2020) (finding "control

persons" for the purposes of Section 20(a) liability where Defendants were "high-level officers of the [c]ompany during the [c]lass [p]eriod, with control over the [c]ompany's SEC filings"). And Plaintiff need not name Mallinckrodt as a defendant in this action for Plaintiff's Section 20(a) claim to proceed. *See In re Suprema Specialties, Inc. Sec. Litig.*, 438 F.3d 256, 285 (3d Cir. 2006) ("A plaintiff need only establish the controlled person's liability.") While Defendants contend that Plaintiff did not plead culpable participation, "the 'overwhelming trend' in the Third Circuit is that culpable participation need not be pled to survive a motion to dismiss." *See Zhengyu He*, 2020 WL 3169506, at *13. The Court, accordingly, finds that Plaintiff has stated a claim under Section 20(a).

IV. CONCLUSION

For the foregoing reasons, Defendants' Motion to Dismiss is denied as to Count One and Count Two. An appropriate order will follow.

/s/ Michael A. Shipp
MICHAEL A. SHIPP
UNITED STATES DISTRICT JUDGE